

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Center for Tobacco Products**

**Office of Science**

**Division of Regulatory Project Management**

Effective Date: December 14, 2018

**1. Division of Regulatory Project Management (DCFDA).**

- A. Directs the tobacco product review process from initial submission to the time of regulatory action.
- B. Serves as the regulatory expert and primary point of contact for communications with regulated entities including industry and researchers related to product submissions.
- C. Develops and implements policies and procedures governing the submission and review of applications and other regulatory submissions including substantial equivalence, pre-market tobacco applications, and modified risk tobacco product applications.

**2. Regulatory Project Management Branch 1 (DCFDA1)**

- A. Coordinates scientific projects including product review activities.
- B. Performs administrative and regulatory screening of applications and other submissions.
- C. Develops and implements policies and procedures governing the development of product standards and regulatory submissions not addressed by other branches.

**3. Regulatory Project Management Branch 2 (DCFDA2)**

- A. Coordinates scientific projects including product review activities.

- B. Performs administrative and regulatory screening of applications and other submissions.
- C. Develops and implements policies and procedures governing the development of product standards and regulatory submissions not addressed by other branches.

**4. Regulatory Project Management Branch 3 (DCFDA3)**

- A. Coordinates scientific projects including product review activities.
- B. Performs administrative and regulatory screening of applications and other submissions.
- C. Develops and implements policies and procedures governing the development of product standards and regulatory submissions not addressed by other branches.

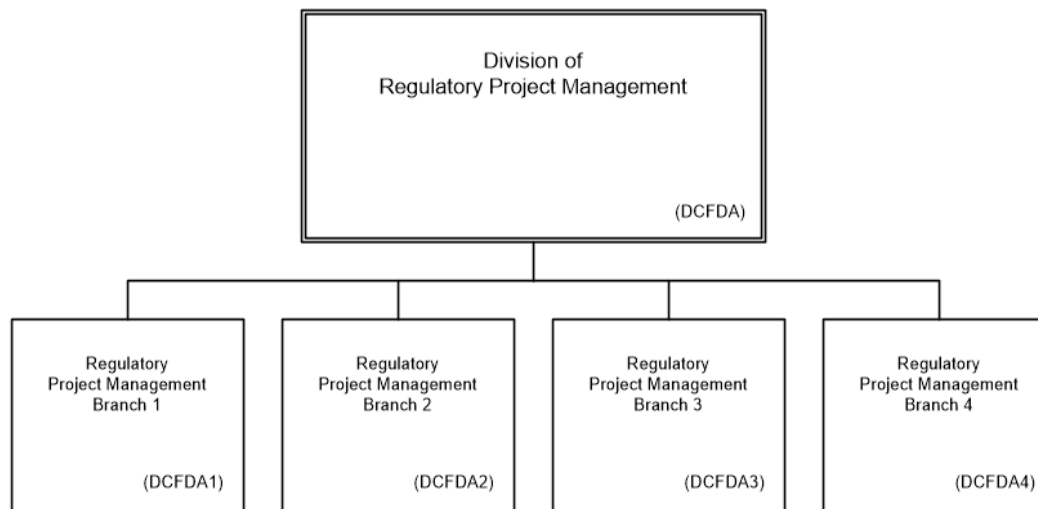
**5. Regulatory Project Management Branch 4 (DCFDA4)**

- A. Coordinates scientific projects including product review activities.
- B. Performs administrative and regulatory screening of applications and other submissions.
- C. Develops and implements policies and procedures governing the development of product standards and regulatory submissions not addressed by other branches.

**6. Authority and Effective Date.**

The functional statements for the Division of Regulatory Project Management were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products  
Office of Science  
Division of Regulatory Project Management**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Office of Science, Division of Regulatory Project Management organization structure depicting all the organizational structures reporting to the Division Director:

Division of Regulatory Project Management (DCFDA)

The following branches report to the Division of Regulatory Project Management (DCFDA):

Regulatory Project Management Branch 1 (DCFDA1)

Regulatory Project Management Branch 2 (DCFDA2)

Regulatory Project Management Branch 3 (DCFDA3)

Regulatory Project Management Branch 4 (DCFDA4)